IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and ABBOTT LABORATORIES, INC., Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	**REDACTED PUBLIC VERSION** Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))

MEDTRONIC'S ANSWERING BRIEF IN OPPOSITION TO ABBOTT'S MOTION TO LIFT STAY OF PROCEEDINGS ON ABBOTT'S MOTION FOR PERMANENT INJUNCTION AS TO MEDTRONIC'S ENDEAVOR

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NATURE AND STAGE OF PROCEEDINGS

On February 26, 2008, Abbott filed its Motion To Lift Stay Of Proceedings On Abbott's Motion For Permanent Injunction As To Medtronic's Endeavor (D.I. 824) (the "Motion"). This is Medtronic's answering brief in opposition to the Motion.

SUMMARY OF ARGUMENT

Abbott's Motion seeks the extraordinary remedy of a permanent injunction on a product – the Endeavor drug-eluting stent – that never has been at issue in this case. In doing so, Abbott's Motion omits the following crucial facts:

- Endeavor was not identified as an accused device in any Complaint or infringement contentions, which focus has been solely on bare-metal stents. Neither Endeavor nor any other drug-eluting stent has ever been addressed in this 10-year-old litigation. (D.I. 734 ¶¶ 2-3; *see also* D.I. 312.)
- Abbott's request for injunctive relief against Endeavor raises several new issues that have not been the subject of discovery or briefing and that must be considered before an injunction can be addressed.
- For example, Endeavor raises new issues regarding the propriety of an injunction under the Supreme Court's decision in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006). Medtronic was *prevented* by Abbott from obtaining discovery in connection with Endeavor and other drug-eluting stents during the last round of *eBay* discovery concerning bare-metal stents.
- The jury trial on the bare-metal stents at issue was conducted under the pre-*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) law of obviousness.

Any proceeding as to Endeavor should be conducted under the current law of obviousness.

- Additional discovery and briefing with respect to Endeavor would significantly delay an appeal and hence a final resolution of the liability issues relating to the adjudicated bare-metal stent products in this case.

Consequently, Medtronic requests that the Court deny Abbott's Motion. As a matter of fundamental fairness, Abbott should not be allowed to take a 10-year procedural shortcut with respect to a product that requires extensive new discovery and investigation. Because any adjudication as to Endeavor will inevitably delay the rest of the case (including final resolution of the case by the Federal Circuit), Medtronic respectfully submits that the Court should proceed with its decision regarding the propriety of an injunction on the bare-metal stent products currently at issue. The propriety of an injunction as to Endeavor should be taken up separately after due consideration of the issues already before the Court.

STATEMENT OF FACTS

The relevant facts are set forth in the Argument section below.

ARGUMENT

I. ANY ENDEAVOR-RELATED LITIGATION SHOULD PROCEED SEPARATELY FROM THE BARE-METAL STENT-RELATED LITIGATION

A. Endeavor Presents Several New Issues Under The *eBay* Factors

This case is about bare-metal stents and has been about bare-metal stents for the past 10 years. Abbott's attempt to seek permanent injunctive relief against the Endeavor drug-eluting stent – a device that has never been part of this case – raises several new considerations that have not been addressed in this litigation. Most importantly, it raises completely new issues regarding

the application of the *eBay* factors to an entirely different product line that has recently emerged from years of development, clinical trials, and regulatory oversight.

In *eBay*, the Supreme Court reaffirmed that a plaintiff seeking a permanent injunction must satisfy the traditional four-factor test for such equitable relief:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

547 U.S. at 391.

Application of *eBay*'s "public interest" prong, for example, would require an analysis of the relative safety and efficacy of Endeavor as compared to other available drug-eluting stents. The limited evidence submitted by Abbott in support of its Injunction Motion indicates that Endeavor may be associated with fewer dangerous side effects than at least one of the two competing drug-eluting stents. (*See* D.I. 730 Ex. 3 at 1) (noting that patients treated with Endeavor had a statistically significant lower rate of non-Q-wave myocardial infarctions (heart attacks) than Cordis's Cypher drug-eluting stent). The factual record on this point is wholly undeveloped, however, with no opportunity for discovery or briefing by Medtronic to date.

Indeed, in accordance with the Court's original Order staying the proceedings with respect to Endeavor, Medtronic *did not address* Abbott's request for relief against Endeavor in its answering brief to the Injunction Motion, and Medtronic *was not permitted* to take any discovery regarding Endeavor or other drug-eluting stents. In fact, Abbott objected to each of Medtronic's discovery requests to the extent that they sought "information related to drug-eluting stents and/or the drug-eluting stent market" as beyond the scope of permissible discovery. (*See, e.g.*, Abbott's Responses And Objections To Defendant's First And Second Requests For

Production Of Documents And Things Regarding The *eBay* Factors at Gen. Obj. No. 6. (attached hereto as Exhibit A).) Abbott also made clear prior to depositions (and objected on the record during depositions) that its witnesses would not testify with respect to any evidence bearing on Endeavor or drug-eluting stents. (*See, e.g.*, Sept. 13, 2007 Letter from Abbott's counsel to Medtronic's counsel regarding the scope of testimony of Abbott's expert witness, Dr. Kahn (attached hereto as Exhibit B); Deposition Transcript of David C. Pacitti, Sept. 28, 2007, at 253:7-257:11 (attached hereto as Exhibit C).)

Endeavor presents several other novel issues that must be assessed under *eBay*, including the substantial hardship to Medtronic if its new drug-eluting stent product is enjoined, and the unfairness of an injunction as a remedy here in light of Abbott's six-year partnership with Medtronic to bring Endeavor to the U.S. market [redacted] It is beyond dispute that before Abbott attempted to inject Endeavor into the permanent injunction phase of this case, none of these issues had ever been mentioned, and there has never been any opportunity for discovery as to these issues here.

In view of the scope of the never-before-addressed *eBay* issues regarding Endeavor, as well as fundamental due process considerations, Abbott's request for an injunction against Endeavor is extremely premature and will require considerable time for discovery and briefing. When Abbott originally filed its Injunction Motion, the Court granted Medtronic a month and a half to conduct discovery related to the application of the *eBay* factors to the accused bare-metal stents, as well as additional time for briefing. (D.I. 756.) At the time, Abbott argued that Medtronic's *eBay* discovery with respect to the accused bare-metal stents should be limited to areas that could not have been "pursued during the pre-trial discovery period." (D.I. 743 at 2.)

Here, by contrast, because Endeavor and other drug-eluting stents *have never been a part of this 10-year litigation*, Medtronic will require a significantly longer *eBay* discovery and briefing period. Given that Endeavor and drug-eluting stents could not have been "pursued" at all during pre-trial discovery, due process mandates a much longer discovery and briefing period.

B. Endeavor Should Be Litigated Under The Current Law

In addition to *eBay*'s clarification of the factors relevant to the issuance of an injunction, patent law has evolved in other ways since the jury trial in 2005. One notable example is the Supreme Court's recent decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), which rejected the Federal Circuit's rigid application of the "teaching, suggestion or motivation" test for obviousness that applied at the time of the jury trial. Any proceedings related to Endeavor should be conducted under the correct standards. *See Harper v. Va. Dep't of Taxation*, 509 U.S. 86, 97 (1993) ("When [the Supreme] Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and as to all events, regardless of whether such events predate or postdate . . . announcement of the rule.").

C. Introducing Endeavor Into This Case Would Further Delay The Resolution Of This Ten-Year-Old Litigation

As the Court is aware, Medtronic has been unable to obtain appellate review of the infringement verdict, notwithstanding its unusually long pendency. Without final resolution of the case on appeal, Medtronic's stents have been the subject of public uncertainty for nearly three years on the basis of an infringement verdict, which the Court has acknowledged was based on a close question of claim construction and may be reversed by the Federal Circuit. (*See* D.I. 637 at 1711:8-19; D.I. 822 at 32:8-20.)

Abbott delayed the appeal once in this case by seeking a permanent injunction after judgment had been entered and then seeking to dismiss Medtronic's appeal. Now, eight months later, Abbott's Injunction Motion against the adjudicated devices has been fully briefed and argued and is pending decision. Once the Court rules on Abbott's Injunction Motion as to the accused bare-metal stents, the appeal will be ripe and can proceed expeditiously.

Permitting Abbott to sweep the Endeavor drug-eluting stent into this case, however, would further delay the appeal process. As described above, Abbott's request for an injunction against Endeavor, and due process, will require a number of additional months for discovery, and then a reasonable time for briefing. By the time the Injunction Motion has been fully briefed and argued as to Endeavor, a significant amount of additional time will have passed. To permit such delay for a product that was never adjudicated (much less accused) is unnecessary for the case to be ripe for appeal and would be highly prejudicial to Medtronic.

On the other hand, if the Court requires Abbott to file for separate relief against Endeavor, this will allow the appeal to move forward and proceed to a final resolution on liability to the benefit of the Court and the parties.

II. ABBOTT'S ATTEMPT TO BRING ENDEAVOR WITHIN THE SCOPE OF ITS PROPOSED INJUNCTION ORDER IS CONTRARY TO LAW

Notwithstanding that Endeavor has not been adjudicated (and interjects considerable additional issues into this case), Abbott suggests that Endeavor is the proper subject of this bare-metal stent litigation because it uses as its platform Medtronic's Driver bare-metal stent, arguing that Endeavor is "not colorably different" from or "contain[s] or use[s] the infringing stents." (D.I. 727 at 26; *id.* at 17-18.). In doing so, Abbott relies heavily on *KSM Fastening Systems, Inc. v. H.A. Jones Co.*, 776 F.2d 1522 (Fed. Cir. 1985). *KSM* was a pre-*eBay* case, however, that gave no consideration to "the traditional four-factor framework that governs the award of

injunctive relief[.]" *See eBay*, 547 U.S. at 394. Instead, *KSM* presumed that a permanent injunction would automatically issue once there was a finding of infringement. In *KSM*, the Federal Circuit ruled that non-adjudicated devices could be enjoined if they "clearly are infringements of the [adjudicated] patent." 776 F.2d at 1526. *KSM* is thus an illustration of the old pre-*eBay* presumption at work. Accordingly, Abbott's argument should be rejected. *See eBay,* 547 U.S. at 393-94.

As described above, there are substantial issues relating to Endeavor that require meaningful discovery and briefing under *eBay*. In these circumstances, the question of whether Endeavor is "no more than colorably different" from Driver for the purposes of infringement is only the beginning of the inquiry, not the end. Indeed, the *KSM* court itself recognized that "[i]f substantial issues need to be litigated, particularly if expert and other testimony subject to cross-examination would be helpful or necessary, the court may properly require a supplemental or new complaint." 776 F.2d at 1531. Although *KSM* was focused on issues relating to infringement, the substantial new issues presented by Endeavor, which require additional discovery and expert testimony, similarly militate in favor of a separate proceeding.[1]

Accordingly, the Court should require Abbott to bring a new action naming Endeavor as an accused device before it may seek relief against Endeavor. Such a result would be consistent with this Court's prior practice in stent cases of requiring a patent holder to accuse a given product before it will be deemed included in the scope of the action. (*See* D.I. 734 ¶¶ 4-5.) This procedure would expedite Federal Circuit review so that the parties and the Court will finally have the benefit of a final resolution of the liability issues regarding the adjudicated bare-metal

[1] For similar reasons, in the event that the Court ultimately orders a permanent injunction as to Medtronic's accused bare-metal stents, Medtronic should not be deemed to be in violation of that order until the new issues raised by Endeavor can be resolved.

stents. Requiring Abbott to file a separate action would allow the Court to either proceed concurrently with the time mandated by due process to conduct discovery and address all relevant issues associated with the Endeavor drug-eluting stent or stay that action pending a decision by the Federal Circuit.

CONCLUSION

For the reasons set forth above, Medtronic respectfully requests that the Court deny Abbott's Motion and enter an order requiring Abbott to file separately against the new Endeavor drug-eluting stent, thereby permitting the case against the currently accused bare-metal stent products to proceed without further delay.

Alternatively, should the Court allow Abbott to accuse the Endeavor drug-eluting stent in this case, Medtronic requests that it be granted six months to take and complete *eBay* discovery. Medtronic then would file its Answering Brief in opposition to Abbott's Injunction Motion against Endeavor, including any challenges to Abbott's claims against Endeavor based on current patent law (*e.g.*, *KSR*), within 60 days of the completion of discovery. If Abbott also intends to take discovery during the *eBay* discovery period, Medtronic requests that a period of nine months be allowed to complete discovery. Abbott did not advise Medtronic or the Court at the time it originally filed its Injunction Motion that it intended to take any discovery, but when the Court allowed Medtronic limited discovery with respect to the bare-metal stents, Abbott filed significant discovery that substantially burdened Medtronic's preparation of a response to Abbott's motion. If Abbott intends to do the same with regard to discovery pertaining to Endeavor, then the discovery period must be longer to accommodate the time needed for both parties to complete discovery.

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on March 19, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to Frederick L. Cottrell, III.

I further certify that on March 19, 2008 I served copies of the foregoing to the following counsel in the manner indicated:

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